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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,850	01/07/2002	Jean C. Gan	5490E-000249	5507

7590 08/09/2005

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/041,850	GAN ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-16 and 22 is/are allowed.
- 6) ☒ Claim(s) 17, 19-21 and 23 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Upon further consideration and in light of the following rejections based on the applicant's amendment, the examiner will rescind the election of species requirement made in the Office Action mailed on June 21, 2004.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 17, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Fulkerson et al. (Pat. No. 4,738,250).

Regarding claim 17, Fulkerson et al. disclose a method of healing soft tissue wounds 38 comprising identifying a soft tissue wound (an inherent step), indicating the use of capacitively coupled electrical stimulation for treatment of the identified soft tissue wound (again an inherent step if one is to use the device of Fulkerson et al.), providing a signal generator 10 in electrical communication with first and second electrodes 30, 31, disposing the electrodes on a skin surface proximate to an identified soft tissue wound (see Fig. 1), generating a time varying electrical signal with the signal generator and delivering the signal to the first and second electrodes (see col. 6, lines 39-49), and generating an electric field in a region of the identified soft tissue wound (the examiner considers the generation of an electric field between the two electrodes to be an inherent outcome of applying a voltage across the electrodes).

Regarding claim 20, Fulkerson et al. disclose the use of a signal generator that is a bipolar DC generator for generating a symmetrical step waveform (see col. 7, lines 50-61). The examiner considers a biphasic square wave to inherently be a symmetrical step waveform (note also Fig. 5B of the present application):

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Regarding claim 23, Fulkerson et al. disclose a method of healing soft tissue wounds 38 comprising providing a signal generator 10 in electrical communication with first and second electrodes 30, 31, disposing the electrodes on a skin surface proximate to an identified soft tissue wound (see Fig. 1), generating a time varying electrical signal with the signal generator and delivering the signal to the first and second electrodes (see col. 6, lines 39-49), and generating an electric field in a region of the identified soft tissue wound (the examiner considers the generation of an electric field between the two electrodes to be an inherent outcome of applying a voltage across the electrodes) for treatment thereof upon delivering said electrical signal to the first and second electrodes.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulkerson et al. (Pat. No. 4,738,250).

Fulkerson et al. do not explicitly disclose the use of an AC generator generating a sine wave voltage (claim 19), or a bipolar DC generator generating a triangular waveform (claim 21). At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to include either of these waveforms in the treatment of soft tissue wounds because the applicant has not disclosed that the generation of an AC sine wave or a DC triangular waveform provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the application of a bipolar DC step waveform (see the rejection of claim 20 above) because the applicant teaches that such a waveform is useful and effective in treating soft tissue wounds (see Fig. 5B). Furthermore, the

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symmetrical bipolar step/square waveform of Fulkerson et al. is intentionally applied to treat soft tissue wounds, just as the applicant's method does. Lacking any criticality in one waveform over the other, those of ordinary skill in the art would have seen the exact choice of waveforms to be a matter of obvious design.

Response to Arguments

6. Applicant's arguments, see the Remarks, filed May 24, 2005, with respect to the Brighton et al. reference have been fully considered and are persuasive. As amended, claims 1 and 17 now require the active step of identifying a soft tissue wound for treatment, thus breathing life and meaning into the claim preamble. The rejection of claims under the Brighton et al. reference has been withdrawn.

Allowable Subject Matter

7. Claims 1-16 and 22 are allowed.

Regarding claim 1, the prior art of record fails to disclose a method of treating a soft tissue wound comprising the steps of identifying the soft tissue wound, and applying an electric field in the identified tissue by generating an electrical signal therebetween at a frequency within a range of 20kHz to 100kHz having a symmetrical waveform with an amplitude within a range of 0.1 to 20 volts peak-to-peak. Although the Brighton et al. reference teaches the use of such a waveform, there is no suggestion to actively identify a soft tissue wound on a patient and to apply the waveform to treat it. There is no suggestion in the prior art of record for modifying the Fulkerson et al. reference to apply such frequencies. Fulkerson et al. explicitly teach that very low frequencies of 0.1 to 0.9 Hz provide good results (col. 7, lines 45-49).

Regarding claim 22, similar comments apply, wherein the steps of disposing first and second electrodes on a skin surface on opposing sides of an *identified soft tissue wound*, and applying an electrical field at the recited frequency range and amplitude, are not disclosed in the prior art.

8. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
August 8, 2005


KENNEDY SCHAETZLE
PRIMARY EXAMINER